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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,184	11/28/2001	Luis Z. Avila	5181	3918

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,184

Applicant(s)

AVILA ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 10, 12 and 13 recite the limitation "PIP" in line 2 of claim 10 and line 1 of claims 12 and 13. There is insufficient antecedent basis for this limitation in the claims, since generic claim 9 reads on a PAG-interacting polymer and does not specifically includes the limitation "PIP".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Balazs et al. (U.S. Patent 4,629,623).

The claimed invention refers to a polymeric composition comprising a mixture of PAG and PIP. Balazs et al. provides highly viscoelastic compositions comprising a mixture of a hyaluronate and a polyethylene oxide (See e.g., col. 2, line 40 to col. 3, line 25) and teaches that the actual

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value of the viscosity of the mixture is greater than the additive value, which would be expected by adding the specific viscosities of polyethylene oxide and hyaluronate (See e.g., Examples 1, 6 and 7).

The compositions disclosed by Balazs et al. meet the limitations of claims 1-4 of the instant application, as they contemplate a composition comprising a mixture of PAG and PIP, having a greater viscosity of either the PAG or the PIP. Thus, Balazs et al. anticipates the claimed invention.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

6. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Spiro et al. (U.S. Patent 6,288,043B1).

Spiro et al. provides an injectable composition comprising hyaluronic acid (HA) crosslinked to a sulfated polysaccharide through a linkage group, which is preferably an amino-terminated polyalkylene glycol (See e.g., col. 2, lines 5-36) and teaches that the HA imparts the property of viscosity and the compositions are formed as a viscous gel (See e.g., col. 3, line 57 to col. 4, line 41 and Table 1).

The compositions disclosed by Spiro et al. meet the limitations of claims 1-4 and 7 of the instant application, as they contemplate a composition comprising a mixture of PAG and PIP, having a

greater viscosity of either the PAG or the PIP. Thus, Spiro et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney et al. (U.S. Patent 6,083,524) in view of Balazs et al.

The claimed invention refers to a polymeric composition comprising a mixture of PAG and PIP and a method comprising applying said mixture to the surface of a substrate to form a gel.

Sawhney et al. discloses water-soluble, biocompatible and biodegradable macromers, wherein the water-soluble region includes polymeric blocks prepared from PEG, polyethylene oxide, poloxamers or natural polymers, and the biodegradable region is a carbonate linkage, such as trimethylene carbonate (TMC) (See e.g., col. 3, line 1 to col. 6, line 62). Sawhney et al. teaches that a PEG backbone can be reacted with TMC, the terminal hydroxyl groups of the TMC-PEG polymer can be reacted with acryloyl chloride to end-cap the polymer with acrylate end-groups, to provide a macromer with reactive functionality, and subsequent reaction of the end groups in an aqueous environment results in a bioabsorbable gel, with similar structures being obtained by using an other PAG, such as a poloxamer (See e.g., col. 9, line 40 to col. 10, line 57). Sawhney

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et al. teaches that the polymers of the invention can be used to seal leaks in tissues, prevent surgical adhesion, controlled delivery of active agents and coatings (See e.g., col. 11, line 32 to col. 14, line 47).

Thus, Sawhney et al. provides compositions comprising PAG macromers comprising crosslinkable groups and biodegradable linkages and methods for forming a gel for medical applications comprising said compositions, and provides the general teaching, that end-capped functionalized PAG monomers can be reacted to form a bioabsorbable gel. Sawhney et al. is deficient in the fact, that it does not specifically disclose PAG-interacting polymers.

Balazs et al. provides highly viscoelastic compositions comprising a mixture of a hyaluronate and a polyethylene oxide (See e.g., col. 2, line 40 to col. 3, line 25) and teaches that the actual value of the viscosity of the mixture is greater than the additive value, which would be expected by adding the specific viscosities of polyethylene oxide and hyaluronate (See e.g., Examples 1, 6 and 7).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the PAG macromers disclosed by Sawhney et al., by reacting said monomers with hyaluronic acid, as taught by Balazs et al., to increase the viscosity of the composition and improve its adhesion to tissues. Because of the teachings of Balazs et al., that mixtures of hyaluronate and water-soluble polyethylene oxide form viscoelastic compositions, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful. Therefore the invention as a

whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

April 30, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600